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DRAFT as of November 4, 2003

CHAPTER 9

HARVESTER: SHELLSTOCK HARVESTING, HANDLING AND SANITATION

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The section number for an existing regulation is noted in brackets [15.01] in the title section. The highlighted section numbers below indicate sections where primary changes have been made since the last version.

Title section:

- 9.01 Compliance
 - (B) See new permits for dealers to commingle product.
 - (C) In particular see sections 15.32 15.35.
- 9.02 Shellstock Washing
 - (C) Cleaning applies to harvesters as well as dealers since they are allowed direct marketing to consumers.
- 9.03 Protection from Contamination
 - (A) [16.17 (B)] and (B) [16.12 (H)]
 - (A) "Handled" replaced "stored" since harvesters are not allowed to "store" product. Sections A and C are combined.
 - (B) Seaweed and wooden hods are localized issues and will be handled through policy
- 9.04 Shellfish Harvester Vessels
 - (A) Section A condensed to remove redundancies. Storage bins replaced with "containers".
 - (A)(3) Text added to clarify that decks are not a requirement.
 - (A)(3)(a) Text simplified to keep clean; removed "approved potable water".
 - (B)(2) Education programs are not necessary to list as a regulation. Removed.
 - (B)(3) The port-o-potty/bucket required will be limited to vessels in use over 6 hours to address the small boat transportation issues. Draggers would still be required to meet these requirements and will be handled by policy.
 - (B)(5) Buckets must be labeled. Added "covering" of product.
- 9.05 Vehicles Used to Transport Shellstock
 - (B)(1) Text simplified to keep clean; removed "approved potable water".
 - (B)(3) Removed: "When necessary"...
- 9.06 [Chapter 48 and 15.08] Shellstock Tagging and Labeling
 - (B) Missing requirements from Model Ordinance (MO) added: Shellfish Type and Quantity; Added title to identify it as a Harvester Tag versus a dealer type tag. Added "printed" information.
 - (B) & (B)(5)(a) References to bulk tagging, which must be done through a dealer, are removed and added to the dealer Chapter 15.18.
 - (B)(5) Text added to explain meaning of harvest "time".
 - (G) Example Harvester tag(s) at the end of the Chapter have been added.
- 9.07 Shellfish Aquaculture

Compliance with the MO Chapter VI; Chapters 10.04(C) and 14.20 registrant sections should be repealed and/or updated for consistency with the MO.

- (A) Leaseholder/harvesters processing shellfish off rafts directly from a lease is considered equivalent to mussels processed aboard draggers hauled directly from the growing area.
- (A) Update Chapter 2 for leaseholder and LPA compliance with Ch 9 and or 15-20.
- (B) The biotoxins section in Chapter 2.90 will need to be updated for consistency with Chapter 9.07(B) and compliance with the MO.

9.08 Shellstock Temperature Control

The entire section is rewritten/condensed to state only the necessary 24-hour requirement. Chapter 9.08 is from applicable MO Chapter VIII Time Temperature Matrices. The Harvester's tag starts this process with the time of harvest on their tags. This is the mechanism to ensure that the harvesters and dealers are in compliance with the appropriate temperature matrix that the Department selects.

9.09 Recall Procedure

The recall procedure in 9.09 requires record keeping and the provision of the time of harvest on the harvester tags under 9.06(B)(5). This is Maine's alternative for compliance with the MO that would otherwise require harvesters to sell fresh shellstock only to certified dealers.

- (A) Text added to clarify that <u>no</u> records are necessary if sold only to certified dealers. The 1-year retention is equivalent to the dealer's requirements.
- (D) Non-compliance consequences added; similar to 15.14(C).
- (D) License indicator of sales only to dealers removed.

CHAPTER 9

HARVESTER: SHELLSTOCK HARVESTING, HANDLING AND SANITATION

9.01 Compliance

- A. Closed Area compliance: Harvest of shellstock is prohibited in areas that are closed due to marine biotoxins pursuant to Chapter 96 and bacterial pollution pursuant to Chapter 95, and in those areas that may potentially be closed by the Department due to marine biotoxins or bacterial pollution. For details about closure lines contact Marine Patrol Division I, west of Port Clyde, Tel. (207) 633-9595 or Marine Patrol Division II, east of Port Clyde, Tel. (207) 667-3373, or telephone the Shellfish Sanitation Hotline at 1-800-232-4733 or on the web at: http://www.maine.gov/dmr/shellfish%20sanitation%20hot%20line.htm.
- B. Commingling of shellstock is prohibited, except that primary dealers, as defined in Chapter 15.02(65), who are authorized by the Department in accordance with Chapter 16.21(C), may commingle shellstock.
- C. Harvesters may not conduct wet storage activities. Wet storage of shellstock is prohibited, except by certified dealers pursuant to a current permit issued by the Department in accordance with Chapter 15.

9.02 Shellstock Washing

- A. Shellstock must be washed such as to be reasonably free of bottom sediments as soon after harvest as practicable.
- B. Shellstock must be culled of dead, broken or gaping shellfish as soon after harvest as practicable and prior to presentation for direct market or delivered to a certified dealer.
- C. The harvester must wash the shellstock using one of the following methods:
 - 1. Wash the shellstock using water from a growing area classified as approved or conditionally approved in the open status at the time and place of harvest; or
 - 2. If shellstock washing is not feasible at the time of harvest, the certified dealer shall be responsible for washing using only water from an approved source.
- D. Shellstock may not be placed in containers of stagnant water.
- E. Depuration harvesters may use growing area water in the restricted or conditionally restricted classification in the open status to wash shellstock at the time and place of harvest.

9.03 Protection from Contamination

- A. Shellstock must be handled in a manner as to be protected from contamination. Shellstock transferred, shipped or transported under conditions creating a potential for contamination, such as with boat motors, engine oil, antifreeze, dead animals, dirty tarps, bilge water, polluted overboard water, closed area water, stagnant water, etc., shall be subject to immediate embargo and/or destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.
- B. Containers used for storing shellstock must be fabricated from safe materials, cleaned and maintained in a manner and frequency as necessary to protect shellstock from contamination.

- C. Shellstock held or washed in closed area water shall be subject to immediate embargo and/or destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.
- D. Once landed, shellstock held or washed in water containing any other macro marine organism(s), such as lobsters, finfish, invertebrates, etc., shall be subject to immediate embargo and/or destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.

9.04 Shellfish Harvester Vessels

A. Vessels

- All harvester vessel operators must ensure that any vessel used to harvest, handle, transfer and/or transport shellstock is properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellstock.
- 2. Vessels and all other equipment coming into contact with shellstock during harvest, handling, transfer and/or transport must be constructed in a manner and with materials that can be cleaned and maintained, repaired and/or replaced.
- Decks or the floor of an open vessel upon which shellstock are placed, and any containers, shall be constructed and or located as to prevent bilge water or polluted overboard water from coming into contact with the shellstock.
- 4. Bilge pump discharges must be located so that the discharge does not contaminate shellstock.
- Boat decks and containers used in the harvest, handling, transfer and/or transport of shellstock must be:
 - (a) Kept clean with water from a growing area in the approved classification or in the open status of the conditionally approved classification:
 - (b) Provided with effective drainage; and
 - (c) Be covered to provide protection from contamination.
- 6. Cats, dogs and other animals must not be allowed on the vessel except for patrol dogs when accompanying security or police officers.
- B. Disposal of Human Sewage From Vessels
 - 1. Human sewage must not be discharged overboard from a vessel used in the harvesting of shellstock while the vessels are in the growing area.
 - 2. An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle must be provided on the vessel to contain human sewage.
 - 3. An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel when the vessel is in use for over 6 hours to contain human sewage.
 - 4. Portable toilets must:
 - (a) Be required on all boats that are in use over 6 hours;

- (b) Be used only for the purpose intended;
- (c) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
- (d) Be emptied only into a sewage disposal system;
- (e) Be cleaned before being returned to the boat; and
- (f) Not be cleaned with equipment used for washing or processing food.
- Use of other receptacles for sewage disposal may be approved by the Department if the receptacles are:
 - (a) Constructed of impervious, cleanable materials and have tight fitting lids;
 - (b) Meet the requirements in Chapter 9.04(B)(4); and
 - (c) Labeled clearly with "Sewage only" or equivalent language.

9.05 Vehicles Used to Transport Shellstock

A. All vehicles used to transport shellstock must be properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellstock.

Vehicles and all other equipment coming into contact with shellstock during transport must be constructed in a manner and with materials that can be cleaned and maintained, repaired and/or replaced.

- B. Containers on vehicles used in the transport of shellstock must:
 - 1. Be kept clean;
 - 2. Provide effective drainage; and
 - 3. Be covered to provide protection from contamination.
- C. Cats, dogs and other animals must not be allowed in any part of the vehicle where shellstock are stored except for patrol dogs when accompanying security or police officers.

9.06 Shellstock Tagging and Labeling

- A. Each harvester licensed by the Department must, prior to landing, securely affix a tag to each container he/she has harvested. If the harvest has occurred at more than one harvest location each container must be tagged at the harvest location and must contain all information necessary to trace the shellfish back to the specific harvest area. Tags must be approved by the Department prior to use and be at least 2 % inches x 5 ¼ inches (6.7 x 13.3 cm) in size and be waterproof and durable.
- B. The harvester's tag must contain legible and indelible printed information arranged in the following order:
 - 1. The title: "Harvester Tag" must be printed on the top of the harvester tag;
 - 2. Harvester's name i.e., the first and last name of the person who harvested the shellstock;

- 3. Harvester's Department license number;
- 4. Date of harvest;
- 5. Time of harvest, for the purpose of determining the time and temperature requirements in Chapter 9.08; the time would be when the harvester has stopped digging at the end of a given low tide and for a vessel, i.e. dragger, time would be the start of harvesting activity, i.e. hauling; and
- 6. The most precise identification of the harvest location, aquaculture lease site or LPA site as is practicable, including the initials of the state (Maine ME), and the Department's designator of the growing area by indexing, administrative or geographic designation. If the Department has not indexed growing areas, then an appropriate geographical or administrative designation must be used; e.g. flat or cove, river or bay, town, state. For example: White's Cove, Nonesuch River, Shellfishville, ME:
 - (a) Off shore vessels harvesting mahogany quahogs must provide identification as to the bay (if appropriate) and/or harvesting zones described by the Department.
- 7. Type and quantity of shellfish;
- 8. The following statement, which must appear in bold capitalized type:
 "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND
 THEREAFTER KEPT ON FILE FOR 90 DAYS"; and
- 9. The following consumer advisory statement from the Maine Food Code (01 Code of Maine Regulations, Chapter 331) regarding shellstock: "RETAILERS, INFORM YOUR CUSTOMERS", and "Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of food borne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."
- C. In the instance where a certified dealer is also the harvester, the dealer's tag may also be used as the harvester's tag.
- It shall be unlawful for any person or persons other than the certified dealer to be in possession of unused certified dealer tags.
- E. The absence of tags as required by this regulation shall be prima facie evidence of a violation of these regulations and shall be grounds for the immediate embargo and/or destruction of the untagged shellstock as being of unsound or unknown quality, and therefore, unsafe for human consumption.
- F. Shellfish tags that do not contain the required information, or are altered or mislabeled, shall be grounds for the immediate embargo and/or destruction of the shellstock as being of unsound or unknown quality, and therefore, unsafe for human consumption.
- G. Example harvester tags are located at the end of this chapter.

9.07 Shellfish Aquaculture

This section applies to persons who are issued an aquaculture lease pursuant to 12 M.R.S.A. §6072 or §6072-A, a limited-purpose aquaculture (LPA) license pursuant to 12 M.R.S.A. §6072-C, or is a registrant pursuant to Chapter 10.04(C) for quahogs, Chapter 14.20 for European oyster or permitted pursuant to Chapter 24.05.

The following graph summarizes the licensing, certification, record keeping and tagging requirements applicable to persons engaged in shellfish aquaculture in territorial waters.

A. Aquaculture permitting and licensing requirements

Activities	Additional license required	Certification (Chapters 15 & 16)	Record Keeping	Tagging
Nursery	None	No ¹	Yes ²	None
Personal Use Recreational Use No sale/barter/trade	None	No	Yes ³	None
Product raised for human consumption No processing Sold in State only	Harvester ⁴	No	Yes⁵	Harvester ⁶
Product raised for human consumption Process, sell or ship to certified dealers, Inter- and Intra State Commerce	Wholesale Seafood ⁷	Yes ⁸	Yes ⁹	Dealer ¹⁰

¹ National Shellfish Sanitation Program, Model Ordinance (as of 04-18-03 throughout) Chapter VI (A-C)

In accordance with Model Ordinance Chapter VI.01 Shellfish Aquaculture, a land based aquaculture facility operator/owner is exempt from being a dealer when nursery shellstock are 6 months or more growing time from market size.

B. Marine Biotoxins

For any marine biotoxin-producing organism for which criteria have not been established under the National Shellfish Sanitation Program Model Ordinance, either cell counts in the water column or biotoxin meat concentrations may be used by the Department as the criteria for not allowing the harvest of shellstock.

1. Paralytic Shellfish Poisoning (PSP); Diarrhetic Shellfish Poisoning (DSP); Domoic Acid (ASP) and Neurotoxic Shellfish Poisoning (NSP)

When local sampling indicates PSP, DSP, ASP or NSP toxin is present in the area, or phytoplankton which may cause PSP, DSP, ASP or NSP toxin are found in the area, then analysis for PSP, DSP, ASP or NSP will be required prior to DMR approval for the harvest or sale of shellstock from the lease or LPA site. A minimum of twelve (12) shellfish must be submitted by the lease or LPA license holder to the DMR Public Health Division Biotoxin Laboratory, by contacting the Boothbay Harbor facility at (207) 633-9555 or the Lamoine facility at (207) 667-2418, at least five (5) business days prior to anticipated harvest.

² Model Ordinance Chapter VI.02(J), DMR Chapter 9.07(D) and Chapter 2.90(E)

³ DMR Chapter 9.07(D) and Chapter 2.90(E)

⁴ 12 MRSA §6601(2), Model Ordinance Chapter VI.02(B)(2)

⁵ DMR Chapter 9.07(D)

⁶ DMR Chapter 9.06

⁷ 12 MRSA §6851 and §6856

⁸ 12 MRSA §6851, §6856 and Model Ordinance

⁹ DMR Chapter 15.24

¹⁰DMR Chapter 15.18-20, Model Ordinance Chapter VI.02(B)(3)

Prior to approving the harvest or sale of shellfish from any lease or LPA site which has submitted shellfish samples to DMR, the DMR may, in its sole discretion, send samples to an accredited analytical laboratory for analysis for PSP, DSP, ASP or NSP toxin.

2. Requirements and procedures

Sample results will be reported to the lease or LPA license holder on a marine biotoxin analysis certificate issued by the DMR Public Health Division.

(a) Monitoring

The cost of monitoring for marine biotoxins, when required under the provisions of this section, shall be paid for by the lease or LPA license holder. When monitoring is required, it must be done prior to the harvest of shellstock from the site for human consumption, or for any other commercial or non-commercial use.

C. Closed Areas

Harvest of shellstock is prohibited in areas that are closed due to bacterial pollution pursuant to Chapter 95. For details about closure lines contact Marine Patrol Division I, west of Port Clyde, Tel. (207) 633-9595 or Marine Patrol Division II, east of Port Clyde, Tel. (207) 667-3373, or telephone the Shellfish Sanitation Hotline at 1-800-232-4733 or on the web at: http://www.maine.gov/dmr/shellfish%20sanitation%20hot%20line.htm. (Chapter 9.01(A))

D. Record keeping

Complete, legible and accurate records of transport, transfer, harvest, and monitoring must be maintained by the lease or LPA license-holder and must be made available for inspection for at least two (2) years. The records must include the:

- Department's Lease ID or LPA license number, site location, date and data related to marine biotoxin analyses;
- 2. Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification status pursuant to Chapter 2.90 and/or Chapter 15;
- 3. Dates of transplanting and harvest;
- 4. Detailed records of sales;
- 5. Water source, its treatment method, if necessary, and its quality in land based systems pursuant to Chapter 15.32, 15.33, 15.34 and or 15.35; and
- Records of the origin and health status of all seed or shellfish stocks reared on the lease or LPA site.
- E. Shellfish harvested from the site must be kept in containers that prevent commingling of different harvest lots.

9.08 Shellstock Temperature Control

Harvested shellstock shall be delivered within 24 hours from the time of harvest (Chapter 9.06(B)(4)) on the shellstock tag to temperature control, i.e. a certified dealer or direct market/consumer within the State of Maine. Time and temperature control requirements must be set in accordance with the Model Ordinance, Chapter VIII Control of Shellfish Harvesting and Chapter 15.02(A)(91). Harvesters shall be informed of any change to the 24-hour requirement by notice in newspapers of general

circulation and press release to the print media if the maximum number of hours for Maine must change.

9.09 Recall Procedure

- A. Complete, legible and accurate records of harvest for sales other than to certified dealers must be maintained by the harvester and must be made available for inspection for at least one (1) year. The harvester transaction log template at the end of this chapter contains the required information for this purpose.
- B. Upon the determination that any shellstock or shellfish products harvested and/or sold by the harvester may have been contaminated with biotoxins, sewage, or any other poisonous or deleterious substances, or is otherwise of unsound or unknown quality, and therefore, unsafe for human consumption, the Department shall:
 - 1. Immediately notify the harvester that shellstock or shellfish products are being recalled;
 - 2. Specify the affected harvest area and date of harvest;
 - 3. Require the harvester to provide the following information to the Department, including any and all records regarding the same:
 - (a) The type and quantity of the shellstock or shellfish products harvested;
 - (b) The type and quantity shipped/sold and the name, address, phone number (if available) of the person shipped/sold to; and
 - (c) The quantity of all shellstock and shellfish products remaining in the possession of the harvester and all person(s) reported pursuant to Chapter 9.09(B)(3)(b) above. All products being held shall be considered embargoed.
 - 4. Advise all persons receiving the shellstock or shellfish products from the harvester that the products must not be further sold or shipped and that the products must be retained on the premises for inspection by Department official(s) or the Department's designated representative(s). All receiving and shipping records and invoices for the recalled shellfish or shellfish products must be made available to the Department at the time of the inspection.
- C. The Department official(s) or designated representative(s) shall inspect the shellstock or shellfish products subject to the recall, and shall review all receiving and shipping records and invoices relating to those shellstock or shellfish products. The Department may copy any or all of the receiving and shipping records and invoices and may, at its discretion take custody of the records and invoices for the purposes of inspection and copying. Shellstock or shellfish products, which cannot be determined to be safe, will be subject to immediate embargo and destruction as provided by 12 M.R.S.A. §6856(6).

D. Non-compliance

If the Commissioner determines that an applicant for renewal of a shellfish license is not currently in compliance with shellfish sanitation regulations, failed to report, or has failed to comply with shellfish sanitation regulations during the previous license period, the Commissioner may refuse renewal of the license in accordance with the following procedures:

- 1. The Commissioner shall advise the applicant for renewal by certified mail, return receipt requested, of the refusal and the grounds for this refusal.
- 2. The Commissioner shall advise the applicant for renewal that the applicant has a right to request that an adjudicatory hearing be held before the Department in conformity with 5

M.R.S.A., Chapter 375 subchapter IV. The Commissioner shall advise the applicant that the hearing must be requested in writing and that the written request must be received by the Department no later than 10 days of receipt by the applicant of the notice, by certified mail, of refusal to renew the shellfish certificate.

- 3. If an adjudicatory hearing is requested, the Commissioner shall schedule a hearing with 10 days of the Department's receipt of the written request for hearing, unless a longer period is mutually agreed to in writing.
- 4. Notice of the hearing date, time and location shall be given immediately to the applicant.

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DRAFT as of November 4, 2003

9.06(G) Example Harvester Tags: The superscripts refer to the required information subsection numbers in Chapter 9.06(B) and are not required on the tag.

HARVE	STER TAG ¹
NAME ² :	_DMR LICENSE#3:
HARVEST DATE ⁴ :	TIME ⁵ :
HARVEST AREA ⁶ :	
AND THEREAFTER KE RETAILERS, INFORM YOUR CUSTOMER such as beef, eggs, fish, lamb, poultry, or sl	TACHED UNTILCONTAINER IS EMPTY PT ON FILE FOR 90 DAYS ⁸ S: "Thoroughly cooking foods of animal origin nellfish reduces the risk of food borne illness. By be at higher risk if these foods are consumed
HARVESTER TAG ¹	

HARVESTER TAG ¹
NAME ² :
DMR LICENSE#3:
HARVEST DATE ⁴ :
TIME ⁵ :
HARVEST AREA ⁶ :
_
SHELLFISH TYPE ⁷ :
& QUANTITY ⁷ :

THIS TAG IS REQUIRED TO BE ATTACHED UNTILCONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS⁸

RETAILERS, INFORM YOUR
CUSTOMERS: "Thoroughly cooking
foods of animal origin such as beef,
eggs, fish, lamb, poultry, or shellfish
reduces the risk of food borne illness.
Individuals with certain health conditions
may be at higher risk if these foods are
consumed raw or undercooked.
Consult your physician or public health
official for further information."9

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Harvester Li	cense Numbe	r:			
			SHELLSTOCK TRANSACTION	LOG FOR HARVE	STER
Harvest	Shellstock	Shellstock	Harvest	Date Sold	Qua
Date	Type	Quantity	Location		She

	SHELLSTOCK TRANSACTION LOG FOR HARVESTERS						
Harvest Date	Shellstock Type	Shellstock Quantity	Harvest Location	Date Sold	Quantity of Shellstock Sold	Sold To	